

## REMARKS

Claims 1-19 are pending in the application.

### **The Restriction Requirement**

Restriction is required under 35 U.S.C. 121 and 372, as the application is asserted to contain the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I, Claims 1-15, drawn to products of formula 1.

Group II, Claims 16-19, drawn to methods of using products of formula 1.

The requirement asserts that the inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1, because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

- The compounds of formula 1 do not have a common core structure within the chemical structure of each compound. For example, compounds of formula 1 consist of variables A1, A2, W, X, and D, each which represent very divergent structural cores. Further such examples are given by the Examiner and it is then concluded that therefore there is not a special technical feature present which links the claims as defined by PCT Rule 13.2.

The restriction requirement further asserts that unity is also lacking under 37 CFR 1.475(b) because a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of five combinations. The restriction also states that according to 37 CFR 1.475(c) if an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph 37 CFR 1.475(b), unity of invention might not be present. The restriction states that the claims are drawn to compounds of formula 1 as well as various methods for using these compounds, and according to 37 CFR 1.475(e) the determination of whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

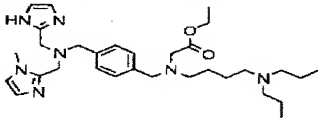
#### **The Election of Species Requirement**

As an additional requirement, with the election of any one of Groups I-II an election of species of a particular species is also required which must include the name and structure of the instantly claimed compound, the location of the species (a) within the claims or (b) within the specification, the claims that read on the elected species, and a definition of the exact substitutions. If Group II is elected the election must further include the name of a single disease to be treated.

### Applicant's Election

In order to be responsive to the requirement for restriction, Applicants elect Group I, including claims 1-15 drawn to products of formula 1, with traverse. Furthermore, in order to be responsive to the election of species requirement, Applicants elect compound 91 with traverse whose name and structural formula are:

[[4-(dipropyl-amino)-butyl]-(4-[[1H-imidazol-2-ylmethyl)-(1-methyl-1H-imidazol-2-ylmethyl)-amino]-methyl)-benzyl)-amino]-acetic acid ethyl ester [Compound No. 91]



The name of the elected Compound 91 is located at page 260 of the specification and the structure of the elected Compound 91 is located in Table 1 at paragraph 176.

The substitutions for Compound 91 are:

- A<sub>1</sub>: monocyclic heteroaromatic ring is an imidazole ring
- A<sub>2</sub> substituted monocyclic heteroaromatic ring is a substituted imidazole ring  
(substituted with methyl group).

$n_1, n_2, n_3$ : 1

$R_1$  to  $R_6$ : hydrogen,

W: benzene ring,

X:  $CH_2$ ,

D: formula 6,

Q:  $NR_{12}$ ,

$R_{12}$ : substituted alkyl group is a substituted methyl group (substituted with alkoxy carbonyl group which is an ethoxy carbonyl group),

Y: formula 7,

$R_{18}, R_{19}$  hydrogen,

$m_3$ : 4,

B: formula 8,

$R_{25}, R_{26}$ : alkyl group is an n-propyl group.

The claims readable on the elected species are claims 1, 2, 3, 6, 7, 9, 13 (12<sup>th</sup> listed compound), and 15. In addition, method claims 16 to 19 are readable on compound 91.

### Traverse

Notwithstanding the election of Group I and the election of species as Compound 91, in order to be responsive to the requirement for election, Applicants respectfully traverse the requirement for restriction and the election of species.

Applicants note that this application is a national stage application, and therefore under unity of invention practice the Examiner must establish that the claims lack unity of invention under PCT Rule 13.1 and 37 C.F.R. 1.475.

In particular, the Examiner is reminded that in determining unity of invention, the criteria set forth in 37 C.F.R. 1.475 must be considered. Specifically, Applicants note that 37 C.F.R. 1.475 provides:

Unity of invention before the International Searching Authority, the International Preliminary Examining Authority, and during the national stage.

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

(e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

Thus, in stating the restriction requirement, the requirement must state why unity of invention is lacking under 1.475. In the instant situation, the requirement does not state why unity is lacking between Groups I and II. Both groups recite the compounds of Formula 1 which provides a special technical feature.

The requirement asserts that compounds of formula 1 do not have a common core structure within the chemical structure of each compound and then concludes that therefore there is not a special technical feature present which links the claims as defined by PCT Rule 13.2. However, formula 1 is present and is the same in both Groups I and II and is the special technical feature.

Furthermore, the requirement does discuss 1.475(b) which permits an international or a national stage application containing claims to different categories of invention to have unity of invention if the claims are drawn only to one of five combinations of categories including a product and a process of use of that product (1.475(b)(2).

However, as stated in the restriction requirement, the Group II claims, claims 16-19 are drawn to methods of using products of formula 1, which is one of the five combinations of categories permitted under 1.475(b), section 2.

Therefore, the requirement for restriction is not proper, and withdrawal thereof is respectfully requested.

Additionally, the election of species requirement is not proper because under unity of invention practice the Examiner must establish that the claims lack unity of invention under PCT Rule 13.1 and 37 C.F.R. 1.475. There are no statements or reasons given as to what constitutes the different species or why they lack unity of invention. Thus, in stating the restriction requirement, and the requirement for an election of species, the requirements must state why unity of invention is lacking at least under 1.475(a). The Examiner is reminded that unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention.

In the instant situation, the restriction requirement and requirement for election do not make the required reference and showing with respect to 37 C.F.R. 1.475. If the requirements are maintained, the requirements must establish that Applicants' claims do

not include therein a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The requirement must show a lack of a special technical feature with respect to the claimed subject matter.

Therefore, the requirement should be withdrawn with respect to each of the groups of invention, and the requirement for election of a single compound.

In view of the foregoing, it is respectfully requested that the Examiner reconsider the requirement for restriction, and the election of species and withdraw the same so as to give an examination on the merits on all of the claims pending in this application.

### CONCLUSION

For the reasons discussed above, it is respectfully submitted that the requirement for restriction and election of species is improper and should be withdrawn.

Withdrawal of the requirement for the restriction and election with the examination of all claims pending in this application is respectfully requested.

Favorable consideration with early allowance of the application is most earnestly requested.

If the Examiner has any questions, or wishes to discuss this matter, please call the undersigned at the telephone number indicated below.

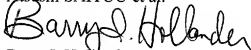
While it is believed that no fees are required for the requested correction of the



SAITOU et al. - Serial No. 10/591,722  
Response to Restriction Requirement  
And Election Of Species Requirement  
Attorney Docket: MOEG-P100

patent application publication, the U.S. Patent and Trademark Office is hereby authorized to charge any fees which may be deemed necessary to Deposit Account No. 19-0089 (MOEG-P100 P33287).

Respectfully submitted,  
Atsushi SAITOU et al.



Barry I. Hollander  
Reg. No. 28,566

GREENBLUM & BERNSTEIN, P.L.C.  
1950 Roland Clarke Place  
Reston, Virginia 20191  
(703) 716-1191

Date: June 12, 2008